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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,628	04/27/2001	Nicolaas M. Lokhoff	P-9695	2393

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EXAMINER	
BRADFORD, RODERICK D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/844,628	LOKHOFF ET AL.
	Examiner	Art Unit
	Roderick Bradford	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3 March 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-14 and 16-35* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 5, 7, 9, 10, 13, 17, 19, 20, 22-25 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Termin et al. U.S. Patent No. 5,378,239 in view of Gates et al. U.S. Patent No. 5,522,875.

Referring to claim 1, 20, 22-24, 31 and 32, Termin discloses an implantable

medical device adapted for implantation comprising:

- An elongated body having a proximal and distal end, the distal end including and inner lumen (Fig. 1)
- A helix residing within the inner lumen and adapted to be extended beyond the distal end of the elongated body, at least a portion of the helix having a diameter that is larger than the diameter of the elongated body when the helix is extended to aid in affixing the helix (Figs. 14).

Gates discloses a fixation assembly coupled to a proximal end of the helix and including a coupling member having a stylet interface slot wherein selective engagement with and rotation of the coupling member via a stylet interface slot wherein selective engagement with and rotation of the coupling member via the stylet interface slot (Fig. 14a), in a respective predetermined direction causes the helix to be extended and retracted, the fixation assembly being adapted to allow for retraction of the helix such that the helix reassumes a compressed configuration within the inner lumen (column 10, lines 12-17).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Termin to include a fixation assembly coupled to a proximal end of the helix and including a coupling member having a stylet interface slot wherein selective engagement with and rotation of the coupling member via a stylet interface slot wherein selective engagement with and rotation of the coupling member via the stylet interface slot, in a respective predetermined direction causes the helix to be extended and retracted, the fixation assembly being adapted to allow for

retraction of the helix such that the helix reassumes a compressed configuration within the inner lumen, such as taught by Gates, as a means to easily change the position of the lead without damaging cardiac tissue.

Referring to claim 4, Gates discloses further comprising a stylet selectively engageable with the stylet interface slot, wherein the rotation of the coupling member is actuated by rotation of the stylet when the stylet is engaged with the stylet interface slot (Fig. 14a).

Referring to claim 5, Gates discloses wherein the diameter of the helix when the helix is extended is substantially constant (Fig. 2b).

Referring to claims 7 and 25, Gates discloses further a conductor coupled to the helix whereby the helix may be used to deliver electrical stimulation (column 2, lines 5-7).

Referring to claims 9 and 10, Gates discloses wherein the helix is formed of a super elastic material and wherein the super elastic material is a shape memory alloy (column 4, line 40-54).

Referring to claim 17, Gates discloses wherein the fixation assembly includes a helical lumen to guide the helix during extension (column 6, lines 50-61).

Referring to claim 13, Termin in view of gates discloses the claimed invention except for wherein the helix lumen configured to allow blood flow to continue in an unimpeded manner at an implant site within the body.

It would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify the device as taught by Termin in view of Gates, to include the helix lumen configured to allow blood flow to continue in an unimpeded manner at an implant site within the body since it was well known in the art to include lumens that allow blood flow to continue unimpeded as means to prevent blood clots within the vessels.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Termin et al. U.S. Patent No. 5,378,239 in view of Gates et al. U.S. Patent No. 5,522,875 as applied to claim 1 above, and further in view of Struble et al. U.S. Patent No. 5,871,531.

Referring to claim 6, Termin in view of Gates fail to disclose wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix. However, Struble discloses wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix (Fig.2) as a means of fitting in smaller vessels and as a means to minimize vessel damage.

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the teachings of Termin in view of Gates to include wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix, as taught by Struble, as a means of fitting in smaller vessels and as a means to minimize vessel damage.

6. Claims 8, 11, 14, 16, 21, 25-29, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Termin et al. U.S. Patent No. 5,378,239 in view of Gates et al. U.S. Patent No. 5,522,875 as applied to claims 1, 7, 20 and 31 above, and further in view of Li et al. U.S. Patent No. 5,716,390.

Referring to claims, 8 and 21 Termin in view of Gates fail to disclose wherein the conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor in a predetermined respective direction. However, Li discloses wherein the conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor in a predetermined respective direction (abstract) as a means to allow the lead to be easily repositioned to another area.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Termin in view of Gates to include wherein the conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor in a predetermined respective direction, as taught by Li, as a means to allow the lead to be easily repositioned to another area.

Referring to claims 11, 29 and 35, Termin in view of Gates fail to disclose wherein the elongated body is further coupled to a sensor to sense a physiological signal. However, Li discloses wherein the elongated body is further coupled to a sensor to sense a physiological signal (column 6, lines 2-4) as a means to make the lead more efficient for sensing different physiological condition.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Termin in view of Gates to include wherein the elongated body is further coupled to a sensor to sense a physiological

signal, as taught by Li, as a means to make the lead more efficient for sensing different physiological condition.

Referring to claims 14 and 34, Termin in view of Gates fail to disclose an implantable medical device further including at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing. However, Li discloses an implantable medical device further including at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing (column 1, lines 65-67 and column 2, lines 4-8) as a means to stimulate different sections of the heart.

It would have bee obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Termin in view of Gates to include at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing, as taught by Li, as a means to stimulate different sections of the heart.

Referring to claims 16 and 28, Termin in view of Gates fail to disclose an implantable medical device further including at least one defibrillation electrode carried on the elongated body. However, Li discloses an implantable medical device further including at least one defibrillation electrode carried on the elongated body (column 4, lines 61-65) as a means to make the lead more efficient.

It would have been obvious to on having ordinary skill in the art at the time the invention was made to modify the teaching of Termin in view of Gates to include at least

one defibrillation electrode carried on the elongated body, as taught by Li, as a means to make the lead more efficient.

Referring to claim 26, Termin in view of Gates and Li discloses the claimed invention except for wherein the elongated body further carries a ring electrode, and wherein the step includes delivering the electrical stimulation between the helix and the ring electrode.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Termin in view of Gates and Li to include delivering the electrical stimulation between the helix and the ring electrode since it was well known in the art that delivering the electrical stimulation between the helix and the ring electrode as a means to more efficiently treat the desired body tissue.

Referring to claim 27, Termin in view of Gates and Li discloses the claimed invention except for wherein the elongated body carries multiple ring electrodes, and further including the step of utilizing one or more predetermined ones of multiple ring electrodes to deliver electrical stimulation to one or more locations within the body.

It would have been obvious to one having ordinary skill at the time the invention was made to modify the device as taught by Termin in view of Gates and Li wherein the elongated body carries multiple ring electrodes, and further including the step of utilizing one or more predetermined ones of multiple ring electrodes to deliver electrical stimulation to one or more locations within the body since it was well known in the art to provide multiple ring electrode as a means of simultaneous provide stimulation to different body tissue.

7. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Termin et al. U.S. Patent No. 5,378,239 in view of Gates et al. U.S. Patent No. 5,522,875also in view of Li. et al. U.S. Patent No. 5,716,390 as applied to claim 11 above, and further in view of Verness et al. U.S. Patent No. 6,119,042.

Referring to claim 12, Termin in view of Gates and Li fails to disclose wherein the sensor is selected from a group of a pressure sensor, O_2 saturation sensor, a temperature sensor, a flow sensor, an impedance sensor, a stroke volume sensor, and a pH sensor. However, Verness discloses wherein the sensor is selected from a group of a pressure sensor, O_2 saturation sensor, a temperature sensor, a flow sensor, an impedance sensor, a stroke volume sensor, and a pH sensor (column 5, lines 34-36) as a means to make the lead more efficient by sensing different physiological parameters.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Termin in view of Gates and Li to discloses wherein the elongated body is further coupled to a sensor to sense a physiological signal and wherein the sensor is selected from a group of a pressure sensor, O_2 saturation sensor, a temperature sensor, a flow sensor, an impedance sensor, a stroke volume sensor, and a pH sensor, as taught by Verness, as a means to make the lead more efficient by sensing different physiological parameters.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Termin et al. U.S. Patent No. 5,378,239 in view of Gates et al. U.S. Patent No. 5,522,875et al. U.S. Patent No. 5,738,239 as applied to claim 17 above, and in further view of Doan et al. U.S. Patent No. 5,456,708.

Referring to claim 18, Termin in view of Gates fail to disclose wherein the helical lumen includes a seal adapted to prevent the ingress of fluids. However, Doan discloses a helical lumen includes a seal adapted to prevent the ingress of fluids (column 3, lines 14-17) as a means to stop body fluids from entering the lead body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Termin in view of Gates to include a helical lumen includes a seal adapted to prevent the ingress of fluids, as taught by Doan, as a means to stop body fluids from entering the lead body.

Allowable Subject Matter

8. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R. Bradford

R.B.

Angela D. Sykes

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